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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 01/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,225	BAICHWAL, ANAND R.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,7,8 and 82-97* is/are pending in the application.

4a) Of the above claim(s) *1-3,7,8 and 82-84* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *85-97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Preliminary Amendments received on July 28, 2004 is acknowledged. Claims 85-97 are included in the prosecution of this application. Claims 1-3, 7-8, and 81-84 are withdrawn as being drawn to a non-elected invention.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 7-8, and 82-84, drawn to a sustained release oral solid dosage form, classified in class 424, subclass 468.

II. Claims 85-97, drawn to a method of preparing a sustained release excipient and preparing an oral dosage form containing the excipient, classified in class 424, subclass 489.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the solid dosage form may be formed by another process than the process claimed in invention II.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Cary Kappel on October 2004 a provisional election was made with traverse to prosecute the invention of II, claims 85-97. Affirmation of

this election must be made by applicant in replying to this Office action. Claims 1-3, 7-8, and 81-84 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 85-88 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 85 and 87 require an inert diluent as one of the components in making the sustained release excipient, however the claims also recite that the diluent is in the amount of **0**-89%. This is vague and indefinite since it is unclear if the inert diluent is a required component, which would require the more than 0% of the diluent. For prosecution purposes, prior art will be applied using both interpretations. Further, clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

Claims 85-86 are rejected under 35 U.S.C. 102(b) as being anticipated by Clare et al (4,693,728).

Clare et al disclose a hydrocolloid blend for controlled release of calcium ions. Example 1 discloses mixing 250 g hydroxyethyl-guar gum (gelling agent) and calcium citrate (cationic

cross linking agent) for five minutes followed by adding water to form a mixture. The mixture was then dried and milled.

Note the 112 indefinite rejection, wherein the claims are unclear if the inert diluent is a required component.

Claims 85 and 87-88 are rejected under 35 U.S.C. 102(b) as being anticipated by Hotko et al (3,456,049).

Hotko et al disclose a gradual release tablet and method of making it. The composition contains an active embedded in a mixture of 5-15% potassium chloride, a fatty substance, 3-15% of alginic acid (gelling agent), and 5-10% of cellulose acetate phthalate. See column 4, lines 70-75. Hotko discloses passing the active, potassium, sterotex, and alginic acid are mixed. Then cellulose acetate phalate (hydrophobic material) dissolved in alcohol is added and mixed thoroughly. The mixture is then dried, milled, and compressed. See examples, particularly example 7 and 9.

Note the 112 indefinite rejection, wherein the claims are unclear if the inert diluent is a required component.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 85-87, 89-93, and 96-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal et al (4,994,276) in view Cohen et al (4,795,642).

Baichwal teaches a slow release tablet for oral administration including a heteropolysaccharide (xanthan gum) and a cross-linking agent and a polysaccharide gum (locust bean gum), inert filler (diluent), and an active agent. See column 4, lines 46-55. The ratio of xanthan gum to locust bean gum is 1:1 and the ratio of the diluent to the gelling agent falls within the recited range of 1:8 to about 8:1. See examples. Polymers such as propylene glycol or hydroxypropylmethylcellulose may be additionally added to the xanthan gum: locust bean gum mixture. See examples 20-28. Baichwal teaches medicaments that are either relatively insoluble or insoluble defined with instant parameters are suitable for the invention. See column 9.

Baichwal et al do not specify the cross linking agent.

Cohen et al a gelatin encapsulated controlled release composition. Cohen teaches the use of a cationic gelling agent to "gel" or coagulate the polysaccharide gums yield a polymeric matrix for drug delivery. The polysaccharide gums taught are vegetable gums. The agents taught are compounds such as citrates, phosphates, tartrates, sulfates, borates, chlorides, and the like, of cations such as sodium, lithium, magnesium, and calcium. See column 3, lines 34-51.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings the teachings of Baichwal et al and Cohen et al and include the instant cross linking agents. One would have been motivated to utilize since Cohen et al teach cationic cross liking agents to "gel" the polysaccharide gums to provide for a polymeric matrix for a drug.

Claims 87-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal et al (4,994,276) in view Cohen et al (4,795,642), in further view of Hotko et al (3,456,049).

As set forth above, Baichwal teaches a method of making a slow release tablet for oral administration including a heteropolysaccharide (xanthan gum) and a cross-linking agent and a polysaccharide gum (locust bean gum), inert filler (diluent), and an active agent. See column 4, lines 46-55. Cohen et al teach the use of a cationic gelling agent to "gel" or coagulate the polysaccharide gums yield a polymeric matrix for drug delivery.

The references do not teach the use of a hydrophobic material as an excipient.

Hotko et al disclose a gradual release tablet and method of making it. Hotko teaches the prior art release tablets wherein a slightly soluble substance is used in the matrices, the release rate is less predictable since the matrices maintain their shape thorough the GI tract; thus they are excreted without releasing the active agent. Hotko also teaches the use of readily soluble components diffuse too easily causing lesions in the GI tract due to high concentration levels. Thus, the use of a soluble component and a insoluble component allows for release in the intestines. See column 1, lines 29-50. Hotko discloses passing the active, potassium, sterotex, and alginic acid are mixed. Then cellulose acetate phalate dissolved in alcohol (hydrophobic

material) is added and mixed thoroughly. The mixture is then dried, milled, and compressed. See examples, particularly example 7 and 9.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings Baichwal et al and Hotko et al and utilize a hydrophobic material. One would have been motivated to do so since Hotko et al teach the use of a soluble carrier component and a insoluble component provides for a predictable release in the intestines and avoids the disadvantages, such as rapid release, of using only a soluble component.

Claims 94-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal et al (4,994,276) in view Cohen et al (4,795,642), in further view of Gulley et al (4,309,405).

As set forth above, Baichwal teaches a method of making a slow release tablet for oral administration including a heteropolysaccharide (xanthan gum) and a cross-linking agent and a polysaccharide gum (locust bean gum), inert filler (diluent), and an active agent. See column 4, lines 46-55. Cohen et al teach the use of a cationic gelling agent to "gel" or coagulate the polysaccharide gums yield a polymeric matrix for drug delivery.

The references do not teach an enteric coating for the slow release tablet.

Guley et al teach a sustained release pharmaceutical composition which includes a core containing a drug and a coating. Guley et al teach the use of an enteric coating for protecting the core during its passage from the stomach to the intestine. Enteric coatings are more soluble at a pH greater than 5 (the pH of the intestine). See column 3, lines 15-30. The amount of coating to core is taught on column 3, lines 51-60.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Baichwal et al, Cohen et al, and Guley et al and use an enteric coating for a sustained release compositions. One would have been motivated to do so since Guley teaches enteric coatings protect the drug core during its passage from the stomach to the intestine, thus allowing the composition to release in the intestine rather than the stomach. Therefore, one would have been motivated to use an enteric coating to provide target release of the active to the intestines.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 85-97 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,709,677, US 6,245,356, US 6,048,548, US 5,512,297, US 5,773,025, and provisional application 10/766688. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim similar subject matter.

Instant claim 85 is directed to the method of preparing a sustained release excipient by dry blending a gelling agent, an inert diluent, and a cationic cross-linking agent.

Instant claim 87 is directed to the method of preparing a sustained release excipient dry blending a gelling agent, an inert diluent, a cationic cross linking agent, and a hydrophobic material.

Instant claim 89 is directed to the method of preparing a sustained release excipient by dry blending a gelling agent, an inert diluent, and a cationic cross linking agent wherein the gelling agent includes a heteropolysaccharide and homopolysaccharide gum in a ratio about 1:3 to about 3:1 and the inert diluent is in a ratio of 1:8 to 8:1.

Instant claim 91 is directed to a method preparing an oral dosage form by dry blending a gelling agent, an inert diluent, a cationic cross linking agent, and a drug wherein the gelling agent includes a heteropolysaccharide and homopolysaccharide gum in a ratio about 1:3 to about 3:1 and the inert diluent is in a ratio of 1:8 to 8:1.

Instant claim 92 is directed to a method preparing an oral dosage form by dry blending a gelling agent, an inert diluent, a cationic cross linking agent, a hydrophobic material, and a drug wherein the gelling agent includes a heteropolysaccharide and homopolysaccharide gum in a ratio about 1:3 to about 3:1 and the inert diluent is in a ratio of 1:8 to 8:1.

Instant claim 93 is directed to a method preparing an oral dosage form by dry blending a xanthan gum and locust bean gum, an inert diluent, a cationic cross linking agent, and a drug wherein the gelling agent includes xanthan gum and locust bean gum in a ratio about 1:3 to about 3:1 and the inert diluent is in a ratio of 1:8 to 8:1.

Instant claim 94 is directed to a method preparing an oral dosage form by dry blending a xanthan gum and locust bean gum, an inert diluent, a cationic cross linking agent, and a drug and coating the tablet with a hydrophobic material.

Instant claim 96 is directed to a method preparing an oral dosage form by dry blending a xanthan gum and locust bean gum, an inert diluent, a cationic cross linking agent, and a drug and coating the tablet with a hydrophobic material wherein the gelling agent includes xanthan gum and locust bean gum in a ratio about 1:3 to about 3:1, the inert diluent is in a ratio of 1:8 to 8:1, and the medicament to gelling agent ratio is 1:3 to 1"8.

Instant claim 97 is directed to the method of preparing a sustained release composition by dry blending a gelling agent, an inert diluent, a cationic cross linking agent, and a medicament.

US patent '677 is directed to a method of preparing a solid dosage form by combining a medicament and a sustained release excipient containing a gelling agent, an enhancing agent (the cationic cross linking agent), ethyl cellulose (hydrophobic material) wherein the xanthan gum to locust bean gum is 1:3 to 3:1 and the inert diluent is in a ratio of 8:1 to 1:8. Dependent claims are directed to coating the tablet with a hydrophobic coating.

US patent '356 is directed to a method of preparing a solid dosage form by combining a medicament and a sustained release excipient containing a gelling agent, an enhancing agent (the cationic cross linking agent), wherein the xanthan gum to locust bean gum is 1:3 to 3:1 and the inert diluent is in a ratio of 8:1 to 1:8.

US patent '548 is directed to a method of preparing a solid dosage form by combining a medicament and a sustained release excipient containing a gelling agent, an enhancing agent (the cationic cross linking agent), wherein the xanthan gum to locust bean gum is 1:3 to 3:1 and the inert diluent is in a ratio of 8:1 to 1:8. Dependent claims are directed to coating the tablet with a hydrophobic coating.

US patent '297 is directed to a method of preparing a solid dosage form by combining a medicament and a sustained release excipient containing a gelling agent, an enhancing agent (the cationic cross linking agent), wherein the xanthan gum to locust bean gum is 1:3 to 3:1 and the inert diluent is in a ratio of 8:1 to 1:8. Dependent claims are directed to coating the tablet with a hydrophobic coating.

US patent '297 is directed to a method of preparing a solid dosage form by combining a medicament of poor solubility, and a 10-99% sustained release excipient containing a gelling agent, 1-20% an cationic cross linking agent, wherein the xanthan gum to locust bean gum is 1:3 to 3:1 and the inert diluent is in a ratio of 8:1 to 1:8. Dependent claims are directed to the inclusion of a hydrophobic material (ethyl cellulose).

US patent '025 independent claims 19 and 33 are directed to a method of preparing a solid dosage form by combining a medicament of poor solubility, and a sustained release excipient containing a gelling agent, an enhancing agent (cationic cross linking agent), wherein the xanthan gum to locust bean gum is 1:3 to 3:1 and the inert diluent is in a ratio of 8:1 to 1:8.

Co-pending application is directed to a method of preparing a sustained release tablet by combining a medicament and a sustained release excipient containing a gelling agent, an enhancing agent (cationic cross linking agent), wherein the xanthan gum to locust bean gum is 1:3 to 3:1 and the inert diluent is in a ratio of 8:1 to 1:8.

The instant application and the US patents cited above are directed to similar subject matter wherein all the patents and applications are directed a method of making a dosage form containing the critical elements of a gelling agent, a cationic cross linking agent, a drug, and an inert diluent.

With regard to the instant claims directed to a method of making a sustained release excipient with the critical elements of a gelling agent, a cationic cross linking agent, and an inert diluent, this is an obvious modification over the above patents and co-pending application since it is obvious to one of ordinary skill in the art to utilize the sustained excipient with a drug of choice to provide an oral dosage form.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Examiner
Art Unit 1616

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